

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Label for the solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for cell associated poultry vaccines.
Read package leaflet before use. Store below 30 °C.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

200 ml
400 ml
500 ml
600 ml
800 ml
1000 ml
1200 ml
1600 ml

4. EXPIRY DATE

EXP: {month/year}

5. BATCH NUMBER

Lot: {number}

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Label for the vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac + CA 126
Marek Vaccine, CVI988 + FC126

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Batch: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Inj. I.M./S.C.
Animal treatment only.

The number of doses per ampoule is presented on the colour coded clip attached to each cane containing the ampoule.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Nobilis Rismavac CA126

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Rismavac + CA 126
(Cell associated Marek's vaccine)
Suspension for injection for chickens.

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

One dose contains:

Live turkey herpes virus strain FC126 $\geq 3.0 \log_{10}$ PFU
Live chicken herpes virus strain CVI-988 $> 3.0 \log_{10}$ PFU

Solvent:

Sterile buffer solution containing:

Sucrose, Pancreatic digest of casein, Monobasic potassium phosphate,
Phenolsulphonphthalein, Water for injections.

The vaccine is supplied in separate units. One consists of the deep-frozen ampoules containing the cell associated vaccine viruses and the other consists of bottles or infusion bags with sterile diluent.

The ampoules are inserted in metal cases and shipped in a liquid nitrogen container.

4. INDICATION(S)

To reduce mortality, clinical signs and lesions after infection with Marek's disease virus (MDV).

Nobilis Rismavac + CA126 may be used for vaccination of day-old chicks and for *in-ovo* vaccination of 18 day embryonated eggs.

5. CONTRAINDICATIONS

Only healthy birds should be vaccinated.
Do not use in birds in lay.

6. ADVERSE REACTIONS

Occasional microscopic lesions might be seen after *in-ovo* vaccination.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Day old chicks

Administer by a single injection of 0.2 ml subcutaneously in the neck or intramuscularly in the leg, after reconstitution in the solvent provided. Injection should be made using an approved repeating syringe or automatic vaccinator. A needle of 20 g x 1/2" should be used to inject the birds. Equipment used for vaccination should be sterile and contain no traces of detergents or disinfectants. The recommended age for vaccination is day-old.

In-ovo vaccination

Inject one dose of the reconstituted vaccine to each 18-day embryonated egg with an appropriate automatic *in-ovo* vaccinator. The actual volume per dose may depend on the settings of the *in-ovo* vaccination equipment.

This should not be less than 50 µl or more than 100 µl. Depending on the volume to be administered the vaccine should be reconstituted according to the instructions below. The egg should be in an upright position with the blunt side up.

| Number of doses per ampoule | Volume of solvent per ampoule needed for reconstitution of the vaccine | | |
|-----------------------------|--|-------------------------------------|------------------------------------|
| | SC / IM (0.2 ml per dose) | <i>in-ovo</i> (0.05 ml per dose) | <i>in-ovo</i> (0.1 ml per dose) |
| 1000 doses | 200 ml | 50 ml | 100 ml |
| 2000 doses | 400 ml | 100 ml | 200 ml |
| 4000 doses | 800 ml | 200 ml | 400 ml |
| 5000 doses | 1000 ml | 250 ml | 500 ml |

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution:

The actual volume of solvent per dose needed for reconstitution of the vaccine may depend on the number of doses per ampoule, the route of administration and for *in-ovo* on the settings of the vaccination equipment. In the table above the volume of solvent per ampoule for the various dose-presentations, routes of administration and settings of the *in-ovo* equipment are given.

Prior to reconstitution the vaccine is thawed. Great care should be taken – see operator warnings. Remove one ampoule from the cane and immediately replace the cane in the liquid nitrogen canister. Thaw the contents of the ampoule rapidly by immersing in water at room temperature. Do not thaw in hot or ice-cold water. Dry the ampoule and shake to disperse contents. After thawing open the ampoule immediately and draw the entire contents into a sterile 5–10 ml syringe using an 18-gauge needle to avoid rupturing the cells. Insert the needle through the stopper of the solvent vial (which should be at room temperature) and draw up slowly a portion of the diluent. Add the contents of the syringe to the remaining solvent. It is important that this is done slowly, allowing the vaccine to run down the side of the bottle. Gently shake the bottle as the vaccine is being mixed.

Withdraw a portion of the vaccine and use to rinse the ampoule. Inject the washing back into the solvent vial. The reconstituted vaccine must be handled gently and administered through wide gauge needles to avoid rupturing the cells. Fill the sterilised repeating syringe / automatic vaccinator according to the manufacturer's instructions. The vial of reconstituted vaccine should be kept in an ice bath when not being used.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport frozen in liquid nitrogen at a temperature below -150 °C.

Thawed ampoules must not be refrozen.

Once diluted the vaccine should be kept at 2 °C to 8 °C and used within 2 hours.

Do not expose reconstituted vaccine to direct sunlight or heat.

Solvent: Store below 30 °C.

Container: Store liquid nitrogen container securely in an upright position in a clean, dry and well-ventilated room separated from the hatching/chicken room.

Do not use after the expiry date stated on the outer label.

12. SPECIAL WARNING(S)

The presence of antibodies to Marek's can affect the efficacy of vaccination.

The vaccine viruses spread; care should be taken to prevent such spread in multi-age sites.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure and variant challenge, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

Interactions

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Incompatibilities:

There is evidence that some antibiotics may interfere with the performance of Marek's vaccines if mixed for administration.

Do not mix with any other veterinary medicinal products.

Operator warning

The operator should be aware of the general precautions to be taken when handling liquid nitrogen and/ or material at very low temperature. Ampoules may explode on sudden temperature changes, therefore the operator should protect himself with gloves and a visor. When removing an ampoule from a cane hold the palm of a gloved hand away from body and face. After handling vaccine operators should wash and disinfect hands with an approved disinfectant.

First aid treatment of frost bite injuries: Warm affected part by immersion in water at $29\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area, seek medical advice.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

15. OTHER INFORMATION

For animal treatment only.

Legal category

POM-VPS

To be supplied only on veterinary prescription.

Pack sizes:

One Type I glass ampoule of 2 ml containing 1000, 2000, 4000 or 5000 doses. Ampoules are stored on a cane.

Bag of 200 ml solvent, bag of 400 ml solvent, bag of 500 ml solvent, bag of 600 ml solvent, bag of 800 ml solvent, bag of 1000 ml solvent, bag of 1200 ml solvent or bag of 1600 ml solvent.

Not all presentation may be marketed.

Marketing authorisation number
Vm 01708/4354

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 13 June 2023

A handwritten signature in black ink, appearing to read 'M. M. M.', is positioned below the approval date.